

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

NATIONAL EMPLOYEES HEALTH PLAN,)	Civ. Action No.
Individually and on Behalf of All Others)	
Similarly Situated,)	<u>CLASS ACTION</u>
)	
Plaintiff,)	COMPLAINT FOR VIOLATIONS OF
)	THE SHERMAN ANTITRUST ACT AND
vs.)	STATE ANTITRUST AND CONSUMER
)	PROTECTION STATUTES
JOHNSON & JOHNSON and JANSSEN)	
BIOTECH, INC.,)	
)	
Defendants.)	
)	
)	<u>DEMAND FOR JURY TRIAL</u>

INTRODUCTION

1. In an effort to maintain and extend its monopoly in the market for its powerhouse biologic medication, Remicade (a.k.a. infliximab), Johnson & Johnson (“J&J”) has worked to suppress competition and raise prices to purchasers of the biologic by imposing a web of exclusionary contracts on both health insurers and healthcare providers. This was done in an effort to maintain its grasp on the nearly \$5 billion annual market for the medication and shut out would-be competitors whose entrance into the market would naturally cause prices for the important drug to decline.

2. According to the U.S. Food and Drug Administration (“FDA”), “Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.” In general, biologics are at the “forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.” Biologics are genetically engineered proteins derived from human genes, typically injected into the bloodstream. They are manufactured in a living system such as a microorganism, or plant or animal cells by combining genetic material from multiple sources.

3. For many years J&J owned patents protecting infliximab and has been rewarded for its invention: between 1998 and 2016, Remicade was the only infliximab product on the market. This position allowed Remicade to become J&J’s best-selling drug by far, generating about \$4.8 billion in U.S. sales in 2016 alone. Remicade is among the best selling drugs in the world. For most uses, at list price Remicade sells for about \$4,000 per infused dose and about \$26,000 for a full year of treatment. The drug (and its biosimilar competitors) is designed to inhibit specific components of the immune system that play pivotal roles in fueling inflammation. These drugs are used to treat many afflictions, including rheumatoid arthritis and Crohn’s disease. Remicade is given by

intravenous infusion in the doctor's office, an infusion center or hospital. Each infusion takes about two hours. The intravenous treatments are generally given three times during the first six weeks of therapy, then every eight weeks thereafter.

4. According to a recently filed complaint by drug giant Pfizer, when Pfizer introduced its competing biologic Inflectra (infliximab-dyyb) in 2016, J&J deployed improper exclusionary tactics to maintain the dominance of its flagship product. Pfizer received marketing approval under the Biologics Price Competition and Innovation Act ("BPCIA") for its biosimilar, Inflectra, in 2016.

5. Congress recognized the growing importance of biologics, as well as the growing costs associated with them, and passed the BPCIA in 2010. The purpose of the BPCIA is to foster meaningful price competition for long-entrenched branded biologic products – with the ultimate goal of lowering healthcare costs. To facilitate price competition, the BPCIA provides an abbreviated FDA approval pathway for "biosimilar" versions of branded biologic drugs. Biosimilars are products that the FDA has determined to have "no clinically meaningful differences" from the already approved biologic (sometimes referred to as the "reference listed drug" or "RLD") in terms of safety, purity and potency. In addition to Pfizer's Inflectra, there is one other biosimilar to Remicade, called Renflexis, manufactured by Samsung Bioepis. Remicade, Inflectra and Renflexis have been approved by the FDA for indications, dosing and administration. While the inactive ingredients vary between the drugs, there are no clinically meaningful differences in safety and efficacy between them.

6. According to Pfizer, on April 5, 2016, it received FDA approval for Inflectra, the first biosimilar to Remicade. Pfizer began shipping Inflectra in November 2016 and set its initial list price, often referred to as the wholesale acquisition cost (or "WAC"), at 15% below the then-current WAC of Remicade. WAC is the manufacturer's published list price to wholesalers or direct

purchasers, not including prompt pay or other discounts, rebates or reductions in price. Samsung Bioepis began selling Renflexis in August 2017.

7. Pfizer began selling Inflectra in November at \$946 a vial, a 15% discount to Remicade's then price of \$1,113. But J&J has retained its pricing power, boosting Remicade's price to \$1,168, a 64% increase since 2011. At launch in August 2017, Samsung Bioepis began selling Renflexis at a 35% discount to the list price of Remicade.

8. Pfizer claims that within weeks of its competing product's launch, J&J began to deploy what it publicly has termed its "Biosimilar Readiness Plan." The core features of the plan are exclusionary contracts that foreclose Pfizer's access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing and hospitals and clinics from purchasing Inflectra or other biosimilars of Remicade despite their lower pricing.

9. J&J's actions to maintain its position took several forms. It entered into exclusive contracts with insurance companies. Insurer decisions regarding reimbursement policies have a dramatic impact on which infliximab product will be stocked by healthcare providers such as hospitals and clinics. Because providers administer infliximab on site (it is an infusion product), they must use their own funds to stock the product, purchasing it for later use and relying upon subsequent reimbursement from insurers to recoup their expenses. Given the cost of biologic drugs generally, and Remicade in particular, there is almost no chance that providers will pay for a product that is not widely covered by insurers for fear of stocking a product that will not be reimbursed after the provider administers it to a patient, as even a single unreimbursed dose may cost the provider in excess of \$4,000. With this knowledge, Pfizer argues J&J induced insurers to enter into contracts that require an explicit commitment not to cover Inflectra at all or to do so only in the rarest of circumstances – in effect, to make Remicade the only covered infliximab.

10. As a direct result of these exclusive dealing contractual commitments, Pfizer alleges, Inflectra is either not listed on an insurance company's medical policy – a published listing of the drugs approved for reimbursement under the insurer's medical benefit – or is designated reimbursable only in so-called "fail first" cases. The "fail first" exception, which requires that Remicade has been tried by and has failed with respect to a given patient before a biosimilar infliximab can be reimbursed, is medically inappropriate and illusory in practice. Because the drugs are biosimilars, if Remicade, which is an infliximab product, does not work for a patient, a physician would turn to a non-infliximab drug, not to Inflectra, which also is an infliximab product and has no clinically meaningful differences from Remicade.

11. The "fail first" contract terms have the same practical effect as a pure exclusive dealing contract in that both operate to exclude a competing biosimilar from qualifying for reimbursement under the insurers plan. According to Pfizer's complaint, J&J has entered into such contracts with all or nearly all national health insurance companies. These "biosimilar-exclusion" contracts, on their own, have foreclosed Inflectra's ability to vie for at least 70% of commercially insured patients in the United States. Samsung's version is similarly foreclosed.

12. J&J has also excluded competition by offering exclusionary rebates and bundling arrangements to insurance company payers. One way J&J has been able to coerce insurers into accepting the exclusionary contract terms noted above is by denying rebates to insurers that decline J&J's exclusivity commitments, thereby imposing a substantial financial penalty. Insurers that decline J&J's offer face a substantial financial penalty, and those that accept receive a payoff (multi-million dollar rebate payments) in return for their commitment to exclude biosimilars. Notably, unlike generic drugs that can be substituted without a new prescription, biosimilars require prescriber approval for changes.

13. The head of J&J's pharmaceuticals business told investors that "the 70% of patients who are [already] stable on REMICADE are highly unlikely to switch." Even if this unsubstantiated claim were true, it means that 30% of the \$5 billion market would be up for grabs in a competitive market. J&J avoided competition for these customers by bundling this economically "incontestable" demand for Remicade with the portion of demand that is "contestable" for biosimilar forms – new patients starting therapy with infliximab or patients who may switch to the lower-cost biosimilar – by threatening to deny rebates on all Remicade prescriptions if any infliximab biosimilar prescriptions are reimbursed, effectively meaning insurers would have to forfeit their rebates and pay J&J's ever-increasing price for the incontestable patients.

14. Pfizer also alleges that J&J bundles rebates on multiple different products, such that insurers that refuse to grant exclusivity to Remicade would be forced to pay higher prices and/or forego enhanced portfolio rebates. The net effect of these anticompetitive bundling practices is that the insurers subject to them have no real choice but to agree to J&J's exclusivity conditions. Pfizer alleges that insurers have led it to understand that the net cost for its version, Inflectra, would need to be low enough to offset the cumulative loss of J&J rebates. Further, Pfizer claims that it and Samsung Bioepis cannot feasibly make up the difference for the J&J rebates on the existing Remicade patient base that insurers would lose if they declined the conditions imposed by J&J. Insurance companies that might want to reimburse Inflectra and Renflexis purchases cannot do so without incurring a substantial financial penalty imposed by J&J and thus potentially placing themselves at a disadvantage relative to insurers accepting J&J's rebates.

15. The effect of J&J's conduct is magnified, because given the gaps in insurance coverage between Inflectra (Pfizer's product) and Remicade, Pfizer alleges that providers have overwhelmingly chosen to stock only Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for

Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by insurance plans that do cover the product. Renflexis faces similar hurdles.

16. Medicare covers Inflectra (and Renflexis), but Pfizer charges that providers have been unwilling to stock Inflectra even for potential use with such government-insured patients. As a result, the government continues reimbursing for Remicade, the more expensive product. As of September 1, 2017, about 90% of healthcare provider accounts using infliximab had purchased no Inflectra at all. Despite some coverage by regional and government plans, Inflectra has secured less than 4% of total infliximab unit sales in the United States as of September 1, 2017, according to Pfizer.

17. With the entry into the market of a competitor, prices of the incumbent biologic should have fallen. Instead, the opposite has occurred. Since the time the FDA approved Inflectra and J&J implemented its publicly stated plan to block biosimilars like Inflectra, J&J has raised the list price of Remicade by close to 9% and increased the amount the U.S. government reimburses for Remicade by more than \$190 per infused dose. J&J's list price increases are not overcome by increased rebates and discounts: Remicade's "average selling price" ("ASP") – which by federal law is an average of a drug's pricing after taking into account discounts, rebates and other price concessions – actually has increased since Inflectra's entry. As of September 2017, Remicade's ASP was more than 10% higher than Inflectra's ASP.

18. J&J has touted its success, noting that it had not "seen much of an impact" from Inflectra's entrance, and that J&J is "especially well-prepared to manage through the Remicade biosimilars." J&J also said it was confident that it could fend off even subsequent biosimilar entrants, including Renflexis, because of its exclusionary contracts: "[W]e have our contracting in place with all the managed care organizations [*e.g.*, health insurers]." The result is that plaintiff

(along with healthcare providers and the U.S. government) has fewer choices and pays more than it should.

PARTIES

19. Plaintiff National Employees Health Plan (the “Plan”) is an “employee welfare benefit plan” under the Employee Retirement Income Security Act and a jointly managed multi-employer plan under the National Labor Relations Act. It represents thousands of employees and their dependents across the country, principally in Michigan and Florida, on whose behalf health and other benefits are provided on a self-funded and insured basis. Medical benefits on a self-funded basis are provided through Blue Cross Blue Shield of Michigan and pharmaceutical benefits on a self-funded basis are provided through OptumRx. Member bills for prescriptions are paid by the Plan to its pharmacy benefits manager. Plaintiff is not generally aware from what source OptumRx purchases its products. Plaintiff is headquartered in Michigan.

20. Defendant J&J is a corporation organized and existing under the laws of New Jersey. J&J’s principal place of business in the United States is located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. J&J is an international pharmaceutical company – one of the largest in the world – and was the sole supplier of infliximab, marketed as Remicade, between 1998 and 2016, when Inflectra came on the market.

21. Defendant Janssen Biotech, Inc. (“Janssen”) is a wholly owned subsidiary of J&J. Janssen is a corporation organized and existing under the laws of Pennsylvania. Janssen’s corporate headquarters are located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

22. The parties listed above as defendants are collectively referred to herein as “Defendants.”

JURISDICTION AND VENUE

23. This Court has original federal question jurisdiction over the Sherman Antitrust Act (“Sherman Act”) claim asserted in this complaint pursuant to 28 U.S.C. §§1331 and 1337 and §§4 and 16 of the Clayton Act, 15 U.S.C. §§15 and 26. This Court also has jurisdiction over this case pursuant to 28 U.S.C. §1332(d) and the Class Action Fairness Act of 2005 (“CAFA”) (28 U.S.C. §1711, *et seq.*), which vests original jurisdiction in the district courts of the United States for any multi-state class action where the aggregate amount in controversy exceeds \$5 million and where the citizenship of any member of the class is different from that of any defendant. The \$5 million amount in controversy and diverse citizenship requirements of CAFA are satisfied in this case.

24. Venue is proper in this District pursuant to §12 of the Clayton Act (15 U.S.C. §22), and 28 U.S.C. §§1391(b)-(d), because a substantial part of the events giving rise to plaintiff’s claims occurred in this District, a substantial portion of the affected interstate trade and commerce discussed below has been carried out in this District, Defendants reside in, are licensed to do business in, are doing business in, have agents in, or are found or transact business in, this District.

25. This Court has personal jurisdiction over of the Defendants because, *inter alia*, each of the Defendants: (a) transacted business throughout the United States, including in this District; (b) marketed and sold infliximab throughout the United States, including in this District; (c) had substantial contacts with the United States, including in this District; and/or (d) engaged in an illegal conspiracy that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

26. The activities of Defendants were within the flow of, were intended to, and did have, a substantial effect on interstate commerce of the United States. Defendants’ products and services are sold in the flow of interstate commerce. The creation, marketing, sale and distribution of

Remicade and the actions complained of in this complaint occur in and substantially affect interstate commerce.

CLASS ACTION ALLEGATIONS

27. Plaintiff brings this action individually and as a class action under Rule 23(a) and (b)(2) of the Federal Rules of Civil Procedure, seeking equitable and injunctive relief on behalf of the following class (the “Injunctive Class”):

All persons and entities in the United States, as defined herein, who purchased, paid and/or provided reimbursement for some or all of the purchase price of Defendants’ infliximab from April 5, 2016 through the present (the “Class Period”). This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries and affiliates; (b) all federal and state governmental entities except for cities, towns or municipalities with self-funded prescription drug plans; (c) all persons or entities who purchased defendants’ infliximab for purposes of resale or directly from Defendants; (d) fully insured health plans (*i.e.*, health plans that purchased insurance covering 100% of their reimbursement obligation to members); (e) any “flat co-pay” consumers whose purchases of Defendants’ infliximab were paid in part by a third-party payor and whose co-payment was the same regardless of the retail purchase price; and (f) any judges or justices involved in this action and any members of their immediate families.

28. Plaintiff also brings this action alleging violations of the antitrust/consumer protection statutes in Counts III and IV on behalf of state classes of infliximab purchasers who are residents of each of the varying states in Counts III and IV who purchased infliximab (the “State Damages Classes”).

29. While plaintiff does not know the exact number of the members of the Classes, plaintiff believes there are at least thousands of members in each Class.

30. Common questions of law and fact exist as to all members of the Classes, thereby making relief appropriate with respect to the Classes as a whole. Questions of law and fact common to the Classes include, but are not limited to:

(a) Whether Defendants unlawfully excluded competition for biosimilar infliximab;

(b) The identify and participants in the scheme;

- (c) The duration of the alleged scheme and the acts carried out by Defendants in furtherance of the suspect conduct;
- (d) Whether the alleged conduct violated the Sherman Act;
- (e) Whether the alleged scheme violated various state antitrust and consumer protection statutes;
- (f) Whether Defendants' conduct caused injury to the business or property of plaintiff and members of the Classes;
- (g) Whether and to what extent Defendants concealed their wrongdoing;
- (h) The effect of the alleged conspiracy on the prices of infliximab in the United States during the Class Period;
- (i) The appropriate injunctive relief for the Injunctive and State Damages Classes; and
- (j) The appropriate classwide measure of damages for the State Damages Classes.

31. Plaintiff's claims arise out of the same common course of conduct giving rise to the claims of the other members of the Classes. Plaintiff's interests are coincident with, and not antagonistic to, those of the other members of the Classes. Plaintiff is represented by counsel who are competent and experienced in the prosecution of antitrust, consumer protection and class action litigation.

32. The questions of law and fact common to the members of the Classes predominate over any questions affecting only individual members, including legal and factual issues relating to liability and damages.

33. Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently and

without the unnecessary duplication of evidence, effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

34. The prosecution of separate actions by individual members of the Classes would create a risk of inconsistent or varying adjudications, establishing incompatible standards of conduct for Defendants.

FACTUAL BACKGROUND

Biosimilars in the United States

35. The Patient Protection and Affordable Care Act, signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (“PHS Act”) to create an abbreviated approval pathway for biological products that are demonstrated to be “highly similar” (biosimilar) to or “interchangeable” with an FDA-approved biological product. These new statutory provisions are referred to as the BPCIA.

36. The goal of the BPCIA is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a the Hatch-Waxman Act), which created abbreviated pathways for the approval of drug products under the Federal Food, Drug, and Cosmetic Act. The BPCIA aligns with the FDA’s longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing.

37. Under the BPCIA, a sponsor may seek approval of a “biosimilar” product under new §351(k) of the PHS Act. A biological product may be demonstrated to be “biosimilar” if data show that the product is “highly similar” to the reference product notwithstanding minor differences in

clinically inactive components and that there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.

38. In order to meet the higher standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product. Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing healthcare provider.

39. Inflectra and Renflexis are currently treated as “highly similar” or “biosimilar” to Remicade. Though it is reported that Pfizer is seeking to have Inflectra be considered “interchangeable” with Remicade for purposes of the BPCIA, any efforts to date have yet to be successful. Thus, before a patient can be moved from Remicade to a competing biologic, a doctor must write a new prescription.

Insurance Coverage Is Critical for Infliximab

40. Insurance coverage and reimbursement are key to the adoption of a product because expensive drugs (like Remicade) will likely not be paid for out of pocket by patients. Most of the people who are prescribed Remicade have insurance or qualify for patient assistance. Because the drug is not one that can be picked up at a pharmacy, but is administered intravenously in a clinic or other institutional setting, it generally is not included under the “pharmacy benefit” of most health plans. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication himself or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and an out-of-pocket payment (usually a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the

physician is affiliated bears financial risk with respect to the drug selected, *i.e.*, the drug is not purchased and stocked in advance by providers at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

41. By contrast, products such as Remicade, sometimes referred to as “medical benefit” products, are administered at a clinic or other healthcare provider site and the provider itself first purchases the drug product for use in the infusion treatment of patients, and then later seeks reimbursement for the drug from a third-party payer (a practice commonly referred to as “buy and bill”). When a treatment is administered, the provider must secure payment for the service, including the cost of the product dispensed (which the provider had to pay up front with its own funds). In this context, the provider has a strong interest in utilizing drugs that are widely covered by insurance, particularly by the major national commercial health insurers and significant regional insurers active in its area.

42. If a drug product is not widely covered, such that there is a risk that coverage might be denied, and providers thus would be burdened with a potential financial loss for what they paid for the product, providers are much less likely to purchase that product – a response that is in line with the providers’ economic interests (to be reimbursed).

43. Commercial insurers typically publish medical policies enumerating the drug products they will cover under the medical benefit and the terms under which they will do so. For example, medical policies may exclude drugs from coverage or they may dictate restrictions on use. Drug manufacturers compete, usually with rebates or other price concessions, to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors or, at a minimum, to achieve “parity,” whereby the competing products have the same restrictions on reimbursement and the patient and/or doctor can choose between them. Securing at

least parity placement is critical, especially for new products seeking to gain traction in the marketplace, and particularly with large insurers, which have tens of millions of covered patients.

J&J's Scheme

44. Part of J&J's exclusionary scheme was revealed in a conference call with analyst Joaquin Duato, worldwide chairman of J&J's pharmaceuticals group, who said the company was gearing up for Pfizer's Remicade rival with a "focused biosimilar readiness plan." That plan includes trying to delay Pfizer's launch via an appeals process and sending out its sales reps to preach the superiority of Remicade's scientific track record and J&J's extensive patient-assistance program. J&J claimed that "70% of patients who are stable on Remicade are highly unlikely to switch."

45. Analysts following J&J also noted the company's "plans to leverage innovative contracting strategies in all channels to fully compete with biosimilars." These so-called innovated strategies ensured that other competing entrants would be unable to grab a foothold in the market. Analysts were so sure that J&J's plan would work that they noted the company "should be able to navigate the threats from the biosimilar entry without any significant share loss in the next 12 months." This was the case even though both Samsung Bioepis's and Pfizer's products were priced significantly below the J&J drug.

46. According to Pfizer, J&J has induced most major health insurers – covering at least 70% of commercially insured patients in the United States – to adopt contractual exclusivity restrictions and to impose outright bans on competing biosimilars' coverage or so-called "fail first" requirements.

47. Pfizer alleges that Cigna and UnitedHealthcare adopted "fail first" requirements, while Anthem excluded its product all together, and Aetna has adopted a complex set of rules that

operated in practice like the “fail first” requirements of Cigna and UnitedHealth. These health insurers cover millions of Americans.

48. Other regional insurers, like certain Blue Cross Blue Shield insurers, have similar “fail first” requirements in place. Those entities similarly cover millions of patients.

49. After Inflectra’s FDA approval in April 2016, and before J&J implemented its exclusionary contracts, Pfizer alleges that health insurers undertook reviews to determine whether there was a medical reason not to reimburse Inflectra or to disfavor it relative to other therapies. Following these reviews, several major health insurance companies – including at least Aetna, Anthem and UnitedHealthcare – classified Inflectra at parity with Remicade. This confirmed that there was no medical reason justifying a restrictive reimbursement policy toward Inflectra. It also meant that, for the time being, Inflectra would be reimbursed without restriction. As a result, the stage was set for Inflectra to begin competing head-to-head with Remicade on a level playing field – and for purchasers to begin receiving the benefits of greater choice and lower prices.

50. These circumstances changed quickly, however. In October 2016, UnitedHealthcare, the nation’s largest health insurer, with more than 30 million covered commercial medical patients, published an update to its medical and site of care policies classifying Inflectra at parity with Remicade for the approved indications (with an effective date of November 1, 2016). This meant that, for UnitedHealthcare, Inflectra would be reimbursed freely and would not be disfavored relative to Remicade. Just weeks later, however, Pfizer alleges that UnitedHealthcare reversed course. UnitedHealthcare classified Remicade as its “preferred” product and instructed that Inflectra would be eligible for reimbursement only in circumstances so limited as to be practically non-existent. Under UnitedHealthcare’s new policy, Inflectra could be reimbursed only where the following conditions were met: (a) the patient must show a minimal clinical response, or an intolerance or adverse reaction, to Remicade; (b) the physician must attest that Inflectra would not lead to the same

adverse responses; and (c) the patient must show no loss of favorable response in established maintenance therapy with Remicade and must not have developed neutralizing antibodies to any infliximab biosimilar product that has made the therapy less effective. As a practical matter, this meant that Inflectra, a drug the FDA approved as having no clinically meaningful differences in safety and efficacy, would not be reimbursed for UnitedHealthcare's more than 30 million commercial medical members and that Remicade would be the exclusive infliximab with UnitedHealthcare – despite the lack of any medical basis for denying those members access to a lower-priced alternative to Remicade. According to Pfizer, this change occurred after J&J induced UnitedHealthcare to enter into an exclusive deal by threatening to penalize UnitedHealthcare with the loss of significant rebates unless UnitedHealthcare agreed to deny coverage of Inflectra.

51. J&J has employed the same approach to secure exclusive deals with many other major insurers. In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers – as adopting any alternative would require the insurer to incur a substantial penalty (*i.e.*, foregoing rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term.

52. In addition to the exclusive contracts, J&J also uses other means to maintain and enhance its monopoly. J&J is able to effectively leverage its large base of existing patients who are stabilized on Remicade. For new patients who may be candidates for infliximab, Pfizer has focused, among other things, on competing for a substantial share of new patient starts – Pfizer calls these patients the “contestable” demand – by pricing Inflectra competitively with both insurers and providers on a unit-for-unit basis. The fact that Inflectra's ASP is lower than Remicade's, and that Renflexis went to market at a price 35% below Remicade's, underscores the cost savings available.

53. To counteract this, Pfizer alleges that J&J threatened to withhold attractive rebates on all Remicade prescriptions – including those for existing patients as well as new ones – unless an insurer agreed to exclusivity. This way J&J is able to leverage the incontestable demand for Remicade to exclude competition for the contestable demand, *i.e.*, it bundles the contestable and incontestable demand. Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J’s exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar. A recent article by two Yale Medical School professors in the *Journal of the American Medical Association* illustrates how the kind of leverage J&J has over existing stable Remicade patients allows it to extract commitments to exclude the biosimilar:

If a biosimilar manufacturer intends to upend the preferred position of the brand by offering a substantial price discount to the [insurer], the branded manufacturer can respond by withdrawing the rebate on the [branded] biologic, creating a “rebate trap.” For any patient continuing the [branded] biologic, a payer’s cost for that patient will double once the rebate is withdrawn Even in [an] optimistic scenario, in which the price of the biosimilar is 60% less than the price of the brand after rebates and discounts, if the payer is only able to convert 50% of its patient users to the biosimilar [because existing patients will tend to stay on the original branded product], the rebate trap ensures that payer total costs actually increase relative to costs prior to biosimilar availability.

To avoid the rebate trap, any strategy to reduce spending on biologics through adoption of biosimilars requires a near-complete switch of patient users from the branded biologic to the biosimilar. However, for many chronic diseases, the proportion of patients new to a given biological therapy is less than 20% of the total patients taking that drug in a given year. The remainder represents a stable base of patients whose disease is well-maintained while they are using current therapy and thus are unlikely to switch [to the biosimilar].¹

54. J&J has further insulated its contracts with insurers from competition by bundling rebates for Remicade with rebates on other products in return for commitments not to cover Inflectra. As part of its “Biosimilar Readiness Plan,” the company plans to leverage other products

¹ Aaron Hakim & Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, *Journal of the American Medical Association* (May 1, 2017), <http://jamanetwork.com/journals/jama/article-abstract/2625049>.

to ensure its monopoly. As J&J's Worldwide Chair for Pharmaceuticals said on a recent earnings call, "We are fully prepared to execute our focused biosimilar readiness plan," including "developing innovative contracts . . . [to] utilize the full breadth of our portfolio." The "full breadth of [J&J's] portfolio" includes several drugs for which Pfizer does not offer any directly competing alternative. Pfizer alleges that J&J has threatened insurers with the loss of rebates on other drugs, as well as Remicade, if they do not agree to exclude Inflectra from coverage.

55. J&J's multi-product bundling, along with its bundling of contestable demand (*i.e.*, new patients) and incontestable demand (*i.e.*, existing Remicade patients), has amplified the anticompetitive effects of J&J's exclusive contracts and made the exclusivity provided by those contracts even more durable. Pfizer argues that insurers have made it clear that Pfizer's net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. But, because of the combined effect of these bundles, Pfizer cannot offset the financial penalties that J&J threatens to impose on insurers who do not agree to exclusivity. As a result, Pfizer is economically prohibited from competing for coverage by the major insurers – even when their exclusive contracts with J&J expire. J&J can use the same bundling strategies to ensure continuation of the exclusionary pattern.

56. Providers are unwilling to stock a drug product where there is significant uncertainty about whether it will be reimbursed by health insurers; because they administer infliximab onsite, providers must expend funds for the product in the first instance, then seek reimbursement after providing treatment. The provider has theoretical recourse against the patient where coverage is denied, but the prospect of securing payment in full from the patient is bleak, especially for drugs as costly as Remicade. As a result, where a significant portion of a provider's patients are insured by plans that have agreed to exclude Inflectra or Renflexis – pursuant to the types of contracts described above – the provider is unlikely to offer the competing products to any of its patients to avoid being caught with no reimbursement.

57. *Bloomberg* has reported on the issue, noting that Ascension Health, a nearly 23,000-bed nonprofit hospital system based in St. Louis, spends \$55 million a year on J&J's Remicade, more than any other drug. "Using Inflectra, part of a new class of medicines called biosimilars, would save it at least \$10 million annually, according to Ascension's chief pharmacist, Roy Guharoy." The article notes that Guharoy planned to integrate Inflectra into care more often until learning that insurers preferred to stay with Remicade. "This we did not expect," Guharoy said. "If the insurance companies force us to use the branded product, of course our hands are tied."

58. USB Global Research noted the same constraints, stating that "contracting and coverage will play a greater role in driving choice of therapy than the preferences of physicians or patients."

59. J&J touts the excluded status of Inflectra in its marketing communications, knowing that doing so will discourage providers from stocking the new biosimilar. J&J markets the "fail first" requirement as a selling point, despite the fact that such a provision is medically inappropriate and despite the FDA's determination that there are no clinically meaningful differences between the two products. J&J touts that Remicade is "Preferred Over Inflectra . . . Inflectra requires trial and failure on Remicade prior to [Inflectra] utilization."

60. Given the widespread gaps in Inflectra's insurance coverage – caused by J&J – providers using infliximab have overwhelmingly chosen to stock only Remicade (which is essentially universally covered given its long tenure and dominant position), rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by commercial or government insurance plans that do cover the product. The effective foreclosure of biosimilars thereby is expanded well beyond the 70% of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of

September 1, 2017, about 90% of healthcare provider accounts using infliximab had purchased no Inflectra at all.

61. In addition to its exclusionary, competition-killing contracts with insurers, J&J has imposed exclusionary contracts on providers themselves (*e.g.*, clinics, hospitals, etc.). After Pfizer introduced Inflectra, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but only if the provider committed to buy Remicade for nearly all of its infliximab needs. To be eligible for rebates, J&J required providers to maintain purchase levels for Remicade at very close to the levels of the year before Inflectra's launch – when Remicade was the only infliximab option. With about 30% of prescriptions in any year representing new patients (and a certain percentage of existing patients exiting therapy each year), this condition also requires providers to use Remicade for new patients if they wish to secure payment from J&J, thus bundling contestable and incontestable demand for Remicade. Like its insurer-level contracts, these contracts as a practical matter make Remicade the exclusive infliximab with participating providers.

62. Multi-product bundling is also used by J&J in its provider-level contracts. As one analyst reported, J&J “bundled several drugs and medical devices together for larger hospitals, which made using [Inflectra] ‘less economical.’” Conditioning rebates linked to other J&J products upon a promise not to do business with Inflectra only exacerbates the exclusionary nature of J&J's contracts.

63. Meanwhile, Pfizer argues that it is prepared to negotiate with providers to make Inflectra the lower priced infliximab option on a per-unit basis and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade. But as with insurer contracts, to secure the right to deal freely with respect to Inflectra (*i.e.*, principally as to new patients), the providers would lose significant J&J rebates on their existing Remicade patient bases.

J&J Possesses Monopoly Power in the Relevant Market

64. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

65. For years before Inflectra's entry, J&J's ASP for Remicade increased, yet Remicade did not lose business. Between 2007 and 2017, Remicade's ASP increased more than 62%. Despite Remicade's price hikes, unit sales of Remicade have actually grown 15% during the period from 2012 to 2016.

66. The introduction of Pfizer's competing product has not eroded Remicade's monopoly power. Instead, since Inflectra was launched, Remicade's ASP has increased without affecting its market position. Ten months after Inflectra's introduction, Remicade still accounted for more than 96% of all infliximab sales.

67. Infliximab is an infusion-administered TNF-inhibiting immunosuppressant with FDA approved indications for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease and plaque psoriasis (together, the "Relevant Indications").

68. The relevant product market is the market for biologic infliximab (the "Relevant Product Market"). Because of the heightened effectiveness of the biologic compared to its biologic competitors and prescription drug analogs that treat the Relevant Indications, those competitors and analogs are not substitutes. The pricing of the biologic bears this out: despite increased prices for Remicade, its sales have not declined. Remicade has over a 90% share of this market.

69. Alternatively, the broadest possible relevant product market is infusion-administered drugs whose approved labeling from the FDA: (a) encompasses one or more of the Relevant Indications, and (b) is without restriction for the applicable Relevant Indication, that is to say, the labeling does not specify that the drug may be used for the applicable Relevant Indication only after

the patient has not responded to another therapy. Remicade enjoys a share of over 60% in the Relevant Product Market, nearly the same share it had before Inflectra entered.

70. Certain non-infusion drugs are also indicated to treat the Relevant Indications. None of those drugs, however, is a reasonable substitute for the infusion-administered products. None of those drugs significantly constrains the prices J&J is able to charge for Remicade.

71. The non-infusion products approved for the Relevant Indications include oral medications (*e.g.*, Xeljanz) and self-injectables (*e.g.*, Humira, Enbrel). These products are patient-administered. Infusion drugs, by contrast, must be delivered by healthcare professionals in a clinical setting (*e.g.*, hospitals or infusion centers) during infusion sessions that take upwards of two hours.

72. Physicians are not likely to switch from prescribing their patients infliximab to prescribing those non-infusion products in response to a small but significant non-transitory change in the price of infliximab.

Barriers to Entry

73. Substantial barriers to entry exist to developing other infusion-administered drug therapies for the Relevant Indications generally and infusion-administered TNF-inhibitors specifically. The development of a new therapy requires tens if not hundreds of millions of dollars and substantial risk, as any new product must survive years of research and development, clinical trials and FDA approval. If left unchecked, J&J's conduct will serve as an additional barrier to entry, as potential new entrants will recognize that they will be unable to break J&J's "rebate trap" and thus to profitably enter the Relevant Product Market – and consequently will not invest the resources necessary to develop biosimilars.

Geographic Market

74. The relevant geographic market for the Relevant Product Market alleged herein is the United States of America and its possessions and territories, as these products are marketed and sold on a national basis.

J&J's Conduct Has Stifled Competition in the Relevant Product Market

75. The acts and practices detailed above have caused substantial harm to the competitive process as well as to purchasers, who have been deprived of the principal benefits of competition – more choices and lower prices. The anticompetitive effects of J&J's conduct are evident in its pricing of Remicade since Inflectra's (and more recently Renflexis's) entry into the market. Despite the fact that Pfizer has offered substantial discounts and a lower ASP to compete for business with insurers and healthcare providers, J&J has been able to increase the price of Remicade without losing any significant share or volume of sales to Pfizer (or any other competitor). J&J's prices for Remicade have been increasing by every measure. J&J has increased Remicade list prices twice since FDA approval of Inflectra. These increases alone raised Remicade's list price nearly 9%.

76. There is no efficiency or cost-reducing justification for J&J's coercive and exclusionary insurer- or provider-level contract terms. J&J has not achieved improved production costs or economies of scale or scope through its contracting strategies. J&J also has achieved no improvements in the Remicade treatment through its contracting strategies. The intent and effect of J&J's conduct was to maintain and strengthen its monopoly position for infliximab.

COUNT I

Violation of 15 U.S.C. §2 Monopolization of the Relevant Product Market

77. Plaintiff repeats and realleges each of the foregoing paragraphs of this complaint and incorporates them by reference as though set forth in full herein.

78. J&J has monopolized the Relevant Product Market in violation of §2 of the Sherman Act.

79. Through the scheme described above, and other conduct likely to be revealed in discovery, J&J has willfully and unlawfully maintained and enhanced its monopoly power in

violation of §2 of the Sherman Act. J&J's scheme constitutes unlawful exclusionary conduct within the meaning of §2 of the Sherman Act.

80. J&J's scheme has stifled competition in the Relevant Product Market and thwarted Congress's purpose in enacting the BPCIA.

81. Among other things, given that: (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually increased since biosimilars entered the market, J&J's pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Product Market.

82. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundled contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

83. As a result of J&J's conduct, and the harm to competition caused by that conduct, plaintiff and the Class have suffered substantial and continuing injuries.

COUNT II

Violation of 15 U.S.C. §2 Attempted Monopolization of the Relevant Product Market

84. Plaintiff repeats and realleges each of the foregoing paragraphs of this complaint and incorporates them by reference as though set forth in full herein.

85. J&J has attempted to monopolize the Relevant Product Market in violation of §2 of the Sherman Act.

86. J&J is violating §2 of the Sherman Act by attempting to implement the anticompetitive scheme set forth above with the specific intent to monopolize the Relevant Product

Market. J&J's scheme constitutes exclusionary conduct within the meaning of §2 of the Sherman Act.

87. There is a dangerous probability that J&J will succeed in monopolizing the Relevant Product Market through its anticompetitive scheme.

88. J&J's scheme has stifled competition in the Relevant Product Market and thwarted Congress's purpose in enacting the BPCIA.

89. Among other things, given that: (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually increased since biosimilars entered the market, J&J's pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Product Market.

90. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundled contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

91. As a result of J&J's conduct, and the harm to competition caused by that conduct, plaintiff and the Class have suffered substantial and continuing injuries.

COUNT III

Violation of State Antitrust Statutes (On Behalf of Plaintiff and the State Damages Classes)

92. **Alabama.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Alabama.

(b) Defendants' conduct had the following effects: Alabama purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Alabama commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Alabama purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Ala. Code §8-10-3. Accordingly, Alabama purchasers seek all forms of relief available under Ala. Code §8-10-3.

93. **Arizona.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Arizona.

(b) Defendants' conduct had the following effects: Arizona purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Arizona commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Arizona purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Ariz. Rev. Stat. Ann. §44-1402, *et seq.* Accordingly, Arizona purchasers seek all forms of relief available under Ariz. Rev. Stat. Ann. §44-1402, *et seq.*

94. **California.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in California.

(b) Defendants' conduct had the following effects: California purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected California commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, California purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated §16720, *et seq.* of the California Business and Professions Code. Accordingly, California purchasers seek all forms of relief available under Cal. Bus. & Prof. Code §16720, *et seq.*

95. **District of Columbia.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the District of Columbia.

(b) Defendants' conduct had the following effects: District of Columbia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected District of Columbia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, District of Columbia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated D.C. Code §28-4509(a). Accordingly, District of Columbia purchasers seek all forms of relief available under D.C. Code §28-4509(a).

96. **Florida.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Florida.

(b) Defendants' conduct had the following effects: Florida purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Florida commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Florida purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Fla. Stat. §542.15, *et seq.* Accordingly, Florida purchasers seek all forms of relief available under Fla. Stat. §542.15, *et seq.*

97. **Guam.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Guam.

(b) Defendants' conduct had the following effects: Guam purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Guam commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Guam purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated 9 Guam Code Ann. §69.20, *et seq.* Accordingly, Guam purchasers seek all forms of relief available under 9 Guam Code Ann. §69.20, *et seq.*

98. **Hawaii.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Hawaii.

(b) Defendants' conduct had the following effects: Hawaii purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Hawaii commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Hawaii purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Haw. Rev. Stat. §480-3, *et seq.* Accordingly, Hawaii purchasers seek all forms of relief available under Haw. Rev. Stat. §480-3, *et seq.*

99. **Iowa.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Iowa.

(b) Defendants' conduct had the following effects: Iowa purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Iowa commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Iowa purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Iowa Code §553.2, *et seq.* Accordingly, Iowa purchasers seek all forms of relief available under Iowa Code §553.2, *et seq.*

100. **Kansas.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Kansas.

(b) Defendants' conduct had the following effects: Kansas purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Kansas commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Kansas purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Kan. Stat. Ann. §50-101, *et seq.* Accordingly, Kansas purchasers seek all forms of relief available under Kan. Stat. Ann. §50-101, *et seq.*

101. **Maine.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Maine.

(b) Defendants' conduct had the following effects: Maine purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Maine commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Maine purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Me. Stat. tit. 10, §1101, *et seq.* Accordingly, Maine purchasers seek all forms of relief available under Me. Stat. tit. 10, §1101, *et seq.*

102. **Michigan.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Michigan.

(b) Defendants' conduct had the following effects: Michigan purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Michigan commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Michigan purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Mich. Comp. Laws §445.771, *et seq.* Accordingly, Michigan purchasers seek all forms of relief available under Mich. Comp. Laws §445.771, *et seq.*

103. **Minnesota.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Minnesota.

(b) Defendants' conduct had the following effects: Minnesota purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Minnesota commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Minnesota purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Minn. Stat. §325D.57, *et seq.* Accordingly, Minnesota purchasers seek all forms of relief available under Minn. Stat. §325D.57, *et seq.*

104. **Mississippi.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Mississippi.

(b) Defendants' conduct had the following effects: Mississippi purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Mississippi commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Mississippi purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Miss. Code Ann. §75-21-9, *et seq.* Accordingly, Mississippi purchasers seek all forms of relief available under Miss. Code Ann. §75-21-9, *et seq.*

105. **Nebraska.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nebraska.

(b) Defendants' conduct had the following effects: Nebraska purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nebraska commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nebraska purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Neb. Rev. Stat. §§59-801–59-802, *et seq.* Accordingly, Nebraska purchasers seek all forms of relief available under Neb. Rev. Stat. §§59-801–59-802, *et seq.*

106. **Nevada.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Nevada.

(b) Defendants' conduct had the following effects: Nevada purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nevada commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Nevada purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Nev. Rev. Stat. §598A.210(2), *et seq.* Accordingly, Nevada purchasers seek all forms of relief available under Nev. Rev. Stat. §598A.210(2), *et seq.*

107. **New Hampshire.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Hampshire.

(b) Defendants' conduct had the following effects: New Hampshire purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Hampshire commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Hampshire purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.H. Rev. Stat. Ann. §356:11(II), *et seq.* Accordingly, New Hampshire purchasers seek all forms of relief available under N.H. Rev. Stat. Ann. §356:11(II), *et seq.*

108. **New Mexico.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New Mexico.

(b) Defendants' conduct had the following effects: New Mexico purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New Mexico commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New Mexico purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.M. Stat. Ann. §57-1-1, *et seq.* Accordingly, New Mexico purchasers seek all forms of relief available under N.M. Stat. Ann. §57-1-1, *et seq.*

109. **New York.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in New York.

(b) Defendants' conduct had the following effects: New York purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected New York commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, New York purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.Y. Gen. Bus. Law §340, *et seq.* Accordingly, New York purchasers seek all forms of relief available under N.Y. Gen. Bus. Law §340, *et seq.*

110. **North Carolina.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in North Carolina.

(b) Defendants' conduct had the following effects: North Carolina purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected North Carolina commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, North Carolina purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated N.C. Gen. Stat. §75-1, *et seq.* Accordingly, North Carolina purchasers seek all forms of relief available under N.C. Gen. Stat. §75-1, *et seq.*

111. **Tennessee.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Tennessee.

(b) Defendants' conduct had the following effects: Tennessee purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Tennessee commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Tennessee purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Tenn. Code Ann. §47-25-101, *et seq.* Accordingly, Tennessee purchasers seek all forms of relief available under Tenn. Code Ann. §47-25-101, *et seq.*

112. **U.S. Virgin Islands.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in the U.S. Virgin Islands.

(b) Defendants' conduct had the following effects: U.S. Virgin Islands purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected U.S. Virgin Islands commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, U.S. Virgin Islands purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated V.I. Code Ann., tit. 11, §1507(4), *et seq.* Accordingly, U.S. Virgin Islands purchasers seek all forms of relief available under V.I. Code Ann., tit. 11, §1507(4), *et seq.*

113. **Utah.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Utah.

(b) Defendants' conduct had the following effects: Utah purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Utah commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Utah purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Utah Code Ann. §76-10-911, *et seq.* Accordingly, Utah purchasers seek all forms of relief available under Utah Code Ann. §76-10-911, *et seq.*

114. **West Virginia.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in West Virginia.

(b) Defendants' conduct had the following effects: West Virginia purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected West Virginia commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, West Virginia purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated W. Va. Code §47-18-20, *et seq.* Accordingly, West Virginia purchasers seek all forms of relief available under W. Va. Code §47-18-20, *et seq.*

115. **Wisconsin.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by illegally monopolizing and attempting to monopolize the market for infliximab in Wisconsin.

(b) Defendants' conduct had the following effects: Wisconsin purchasers paid supracompetitive, artificially inflated prices for infliximab.

(c) During the Class Period, Defendants' illegal conduct substantially affected Wisconsin commerce.

(d) As a direct and proximate result of Defendants' unlawful conduct, Wisconsin purchasers have been injured in their business and property and are threatened with further injury.

(e) By reason of the foregoing, Defendants have violated Wis. Stat. §133.03(1), *et seq.* Accordingly, Wisconsin purchasers seek all forms of relief available under Wis. Stat. Ann. §133.03(1), *et seq.*

COUNT IV

Violation of State Consumer Protection Statutes (On Behalf of Plaintiff and the State Damages Classes)

116. **Florida.** Plaintiff further alleges as follows:

(a) The aforementioned practices by Defendants were and are in violation of the Florida Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. §501.201, *et seq.*

(b) The FDUTPA defines "[c]onsumer" as "an individual; child, by and through its parent or legal guardian; business; firm; association; joint venture; partnership; estate; trust; business trust; syndicate; fiduciary; corporation; . . . or any other group or combination." Plaintiff and the members of the State Damages Classes are "[c]onsumers" within the meaning of Fla. Stat. §501.203(7).

(c) The FDUTPA defines "[t]rade or commerce" as:

[T]he advertising, soliciting, providing, offering, or distributing, whether by sale, rental, or otherwise, of any good or service, or any property, whether tangible or intangible, or any other article, commodity, or thing of value, wherever situated.

“Trade or commerce” shall include the conduct of any trade or commerce, however denominated, including any nonprofit or not-for-profit person or activity.

Fla. Stat. §501.203(8). The advertising, soliciting, offering, selling and furnishing of infliximab by Defendants to plaintiff and the members of the State Damages Classes is “[t]rade or commerce” within the meaning of the FDUTPA. Fla. Stat. §501.203(8).

(d) The FDUTPA provides that “[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.” Fla. Stat. §501.204(1). Defendants’ acts as alleged in this complaint are unconscionable, illegal, unfair and/or deceptive.

(e) The unconscionable, illegal, unfair and deceptive acts and practices of Defendants are violative of the provisions of FDUTPA. Plaintiff and the members of the State Damages Classes have suffered actual damage for which they are entitled to relief pursuant to Fla. Stat. §501.211(2).

(f) Plaintiff, individually and in its representative capacity, is entitled to recover reasonable attorneys’ fees pursuant to Fla. Stat. §501.2105, upon prevailing in this matter.

117. **Hawaii.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in Hawaii.

(b) The foregoing conduct constitutes “unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce” within the meaning of Haw. Rev. Stat. §480-2(a). During the Class Period, Defendants’ illegal conduct substantially affected Hawaii commerce and consumers.

(c) Defendants’ unlawful conduct had the following effects: (1) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Hawaii; (2) Hawaii

purchasers were deprived of free and open competition; and (3) Hawaii purchasers paid supracompetitive artificially inflated prices for infliximab.

(d) As a direct and proximate result of Defendants' conduct, Hawaii purchasers have been injured and are threatened with further injury.

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. §480-2. Accordingly, Hawaii purchasers seek all relief available under Haw. Rev Stat. §480-1, *et seq.*

118. **Nebraska.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold, distributed or obtained in Nebraska.

(b) The foregoing conduct constitutes "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce" within the meaning of Neb. Rev. Stat. §59-1602.

(c) During the Class Period, Defendants' illegal conduct substantially affected Nebraska's commerce and consumers.

(d) Defendants' unlawful conduct had the following effects: (1) price competition for infliximab was restrained, suppressed and eliminated throughout Nebraska; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Nebraska; (3) Nebraska purchasers were deprived of free and open competition; and (4) Nebraska purchasers paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants' conduct, Nebraska purchasers have been injured and are threatened with further injury.

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. §59-1601, *et seq.*, and accordingly, Nebraska purchasers seek all relief available under that statute.

119. **New Mexico.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in New Mexico.

(b) The foregoing conduct constitutes “[u]nfair or deceptive trade practices and unconscionable trade practices in the conduct of any trade or commerce” within the meaning of N.M. Stat. Ann. §57-12-3, in that such conduct resulted in a gross disparity between the value received by New Mexico purchasers and the prices paid by them for infliximab as set forth in N.M. Stat. Ann. §57-12-2E.

(c) During the Class Period, Defendants’ illegal conduct substantially affected New Mexico’s commerce and consumers.

(d) Defendants’ unlawful conduct had the following effects: (1) price competition for infliximab was restrained, suppressed and eliminated throughout New Mexico; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout New Mexico; (3) New Mexico purchasers were deprived of free and open competition; and (4) New Mexico purchasers paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants’ conduct, New Mexico purchasers have been injured and are threatened with further injury.

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. Ann. §57-12-1, *et seq.*, and accordingly, New Mexico purchasers seek all relief available under that statute.

120. **New York.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in New York.

(b) Defendants' illegal conduct substantially affected New York's commerce and consumers.

(c) The conduct of Defendants as described herein constitutes consumer-oriented deceptive acts or practices within the meaning of N.Y. Gen. Bus. Law §349, which resulted in consumer injury and had a broad adverse impact on the public at large, and harmed the public interest of the State of New York in an honest marketplace in which economic activity is conducted in a competitive manner.

(d) As consumers, New York purchasers were targets of the conspiracy.

(e) Defendants made public statements about the price of infliximab that Defendants knew would be seen by New York purchasers. Such statements either omitted material information that rendered the statements made materially misleading or affirmatively misrepresented the real cause of price increases for infliximab. Defendants alone possessed material information that was relevant to consumers, but failed to provide that information.

(f) Because of Defendants' unlawful trade practices in the State of New York, there was a broad impact on New York purchasers who indirectly purchased infliximab. New York purchasers have been injured because they have paid more for infliximab than they would have paid in the absence of Defendants' unlawful trade acts and practices, and are threatened with further injury.

(g) Because of Defendants' unlawful trade practices in the State of New York, New York purchasers who indirectly purchased infliximab were misled into believing that they were

paying a fair price for infliximab, or that the price increases for infliximab were for valid business reasons.

(h) Defendants knew that their unlawful trade practices with respect to the pricing of infliximab would have an impact on New York purchasers and not just Defendants' direct customers.

(i) Defendants knew that their unlawful trade practices with respect to the pricing of infliximab would have a broad impact, causing members of the State Damages Classes who indirectly purchased infliximab to be injured by paying more for infliximab than they would have paid in the absence of Defendants' unlawful trade acts and practices.

(j) During the Class Period, each of the Defendants named herein, directly or indirectly through affiliates they dominated and controlled, manufactured, sold and/or distributed infliximab in New York.

(k) New York purchasers seek actual damages for their injuries caused by these violations in an amount to be determined at trial.

121. **North Carolina.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in North Carolina.

(b) Defendants also took efforts to conceal their agreements from North Carolina purchasers.

(c) The conduct of Defendants as described herein constitutes consumer-oriented deceptive acts or practices within the meaning of N.C. Gen. Stat. §75-1.1, *et seq.*, which resulted in consumer injury and had a broad adverse impact on the public at large, and harmed the public

interest of North Carolina consumers in an honest marketplace in which economic activity is conducted in a competitive manner.

(d) During the Class Period, Defendants' illegal conduct substantially affected North Carolina's commerce and consumers.

(e) Defendants' unlawful conduct had the following effects: (1) infliximab price competition was restrained, suppressed and eliminated throughout North Carolina; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout North Carolina; (3) North Carolina purchasers were deprived of free and open competition; and (4) North Carolina purchasers paid supracompetitive, artificially inflated prices for infliximab

(f) As a direct and proximate result of Defendants' conduct, North Carolina purchasers have been injured and are threatened with further injury.

(g) During the Class Period, each of the Defendants named herein, directly or indirectly through affiliates they dominated and controlled, manufactured, sold and/or distributed infliximab in North Carolina.

(h) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. §75-1.1, *et seq.*, and accordingly, North Carolina purchasers seek all relief available under that statute.

122. **Vermont.** Plaintiff further alleges as follows:

(a) Defendants agreed to, and did in fact, act in restraint of trade or commerce by affecting, fixing, controlling and/or maintaining, at artificial and/or non-competitive levels, the prices at which infliximab was sold in Vermont.

(b) Defendants deliberately failed to disclose material facts to Vermont purchasers concerning Defendants' unlawful activities and artificially inflated prices for infliximab. Defendants owed a duty to disclose such facts, and considering the relative lack of sophistication of

the average, non-business consumer, Defendants breached that duty by their silence. Defendants misrepresented to all consumers during the Class Period that prices for Defendants' infliximab were competitive and fair.

(c) Because of Defendants' unlawful and unscrupulous trade practices in Vermont, Vermont purchasers who indirectly purchased infliximab were misled or deceived into believing that they were paying a fair price for infliximab or that the price increases for infliximab were for valid business reasons.

(d) Defendants' unlawful conduct had the following effects: (1) price competition for infliximab was restrained, suppressed and eliminated throughout Vermont; (2) infliximab prices were raised, fixed, maintained and stabilized at artificially high levels throughout Vermont; (3) Vermont purchasers were deprived of free and open competition; and (4) Vermont purchasers paid supracompetitive, artificially inflated prices for infliximab.

(e) As a direct and proximate result of Defendants' illegal conduct, Vermont purchasers suffered an ascertainable loss of money or property as a result of Defendants' use or employment of unconscionable and deceptive commercial practices as set forth above. That loss was caused by Defendants' willful and deceptive conduct, as described herein.

(f) Defendants' misleading conduct and unconscionable activities constitute unfair competition or unfair or deceptive acts or practices in violation of Vt. Stat. Ann. tit. 9, §2451, *et seq.*, and accordingly, Vermont purchasers seek all relief available under that statute.

PRAYER FOR RELIEF

WHEREFORE, plaintiff requests that the Court enter judgment on plaintiff's behalf and on behalf of the Classes herein, adjudging and decreeing that:

A. The Court determines that this action may be maintained as a class action under Rule 23(a), (b)(2) and (b)(3) of the Federal Rules of Civil Procedure, and direct that reasonable notice of

this action, as provided by Rule 23(c)(2) of the Federal Rules of Civil Procedure, be given to each and every member of the Classes.

B. That the unlawful conduct alleged herein be adjudged and decreed:

(a) An unreasonable restraint of trade or commerce in violation of §2 of the Sherman Act;

(b) Unlawful monopoly maintenance in violation of the state antitrust and unfair competition and consumer protection laws as set forth herein; and

(c) Unlawful attempted monopoly maintenance in violation of the state antitrust and unfair competition and consumer protection laws as set forth herein.

C. Plaintiff and the members of the Damages Class(es) recover damages, to the maximum extent allowed under such laws, and that a judgment in favor of plaintiff and the members of the Damages Class(es) be entered against the Defendants in an amount to be trebled to the extent such laws permit.

D. Plaintiff and the members of the Damages Class(es) recover damages, to the maximum extent allowed by such laws, in the form of restitution and/or disgorgement of profits unlawfully gained from them.

E. Defendants, their affiliates, successors, transferees, assignees and other officers, directors, partners, agents and employees thereof, and all other persons acting or claiming to act on their behalf or in concert with them, be permanently enjoined and restrained from, in any manner, continuing, maintaining or renewing the conduct, alleged herein, or from entering into any other contract or engaging in any other conduct, having a similar purpose or effect, and from adopting or following any practice, plan, program or device having a similar purpose or effect.

F. Plaintiff and the members of the Damages Class(es) be awarded restitution, including disgorgement of profits Defendants obtained as a result of their acts of unfair competition and acts of unjust enrichment.

G. Plaintiff and the members of the Classes be awarded pre- and post- judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of this complaint.

H. Plaintiff and the members of the Classes recover their costs of suit, including reasonable attorneys' fees, as provided by law.

I. Plaintiff and members of the Classes have such other and further relief as the case may require and the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, of all issues so triable.

DATED: September 28, 2017

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